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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,026

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Bror Morein

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EXAMINER

LUCAS, ZACHARIAH

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,026	Applicant(s) MOREIN ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3, 11, 16, 17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 12-15 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 lists</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-19 are pending in the application.

Election/Restrictions

2. Applicant's election with traverse of Group I, and the species wherein the composition further comprises an antigenic molecule, and the iscom comprises subfragment A of the Quillaja saponin fraction A in the reply filed on June 12, 2008 is acknowledged. The traversal is on several grounds.

First the Applicant asserts that 27 CFR 1.475 mandates that the inventions be examined together. This argument is not found persuasive because rule 475 only requires that inventions of the indicated different groups be examined together where the claims are drawn "only to one of the following combinations of categories." In the present case, the claims are drawn both to a product and a process for the manufacture of the product and to a process and an apparatus for carrying out the process. Thus, as unity of invention is lacking as indicated in the restriction requirement and in the rejections below, the argument is not found persuasive.

Next, Applicant argues that the various species are not mutually exclusive. The argument is not found persuasive because, while the claims do not specifically exclude the other species, the indicated claims recite limitations disclosed for a first species but not the second, and a second claim recites limitations for the second claim and not for the first. See, MPEP 806.04. As the various species have distinct structures and limitations, the Applicant's arguments in traversal are not found persuasive.

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However, upon further consideration, the species election between Fractions A and C of Quil A are withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 3, 11, 16, 17, and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 12, 2008.

4. Claims 1, 2, 4-10, 12-15, and 18 are under consideration.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on September 23, 2005, September 11, 2007, and June 13, 2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

It is noted that only the abstract of reference R of the September 2007 IDS has been submitted. The reference has therefore been considered only to the extent of this abstract.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 4-8, 14, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There are two grounds of rejection.

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The first ground of rejection applies to claims 1, 2, 4-8, and 18. Claim 1 is treated as representative. This claim is drawn to a method for preparing an antigen composition comprising “using an iscom particle as an adjuvant.” It is not clear from the claim what the scope of the claimed invention is. The sole method step provided in the claim is the use of the iscom as an adjuvant. However, the claim reads on a method for “preparing an antigen composition.” It is therefore not clear if the claim is implicitly requiring that the iscom particle be combined with the antigen composition to form a single composition comprising both the iscom and the antigen, or of the claim is merely requiring that an iscom be used as an adjuvant without specifically requiring the combination of the iscom and the antigen prior to administration.

The second ground of rejection applies to claims 8 and 14. These claims are rejected because it is not clear what is meant by reference to “subfragment A and subfragment C or Quillaja saponin Fraction A.” There is no disclosure in the application of such subfragments, and a search of the art provided no identification of such subfragments.

It is noted that the application and art refer to Fractions A and C of the “homogenous” fraction Quil A from the tree *Quillaja saponaria* Molina. See e.g., Cox et al. WO 96/11711, pages 1 (lines 23-27) and page 3 (lines 22-25). See also, page 8 of the present application. Claims 8 and 14 are therefore being interpreted for the purposes of this action as though they refer to Fractions A and C of Quil A.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 6, 9, 10, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wechter et al. (U.S. 6,177,081). These claims are drawn to compositions, and methods of preparing such, comprising a liver microorganism, such as a virus, and an iscom particle.

Wechter teaches live attenuated viruses for use in vaccines. Columns 8-9. The reference teaches the combination of the attenuated viruses with an iscom. As iscoms are known in the art to comprise glycosides and lipids, the reference also inherently teaches claim 6. The reference therefore anticipates the indicated claims.

10. Claims 1, 2, 6, 7, 8, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Iosef et al. (Vaccine 20:1740-53- of record in the September 2005 IDS). Claims 1, 2, and 6 have been described above. As was indicated above, claim 1 merely requires the use of an iscom particle as an adjuvant. The claim does not appear to specifically require the combination of the iscom with the live microorganism. Claims 7 and 8 are drawn to embodiments wherein the iscom comprises one of Fractions A and/or C of Quil A. However, it is noted that the claims merely require the presence of at least one glycoside fragment from the Fractions, which limitation would be inherently met by the use of Quil A. Claim 18 is drawn to the methods of claim 1 composition comprising the provision of a kit comprising “parts comprising at least one

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compartment containing the at least one live microorganism and at least one compartment comprising the iscom particle” (i.e. a container comprising the iscom, and a container comprising the virus).

Iosef teaches methods for the induction of immune responses in pigs comprising the administration of both a live attenuated virus, and the administration of a non-infectious VLP/iscom vaccine. Page 1743. Because the iscom and live virus vaccines are separately administered, the reference inherently teaches a kit comprising separate containers for the iscoms and live virus. The reference teaches that the iscoms comprise as the saponin Quil A, which, as indicated above, would inherently comprise at least one glycoside fragment from fractions of that saponin formulation. Id., left column. While the reference does not teach the combination of the iscom with the live virus, such is not required by the claims as indicated above. The claims merely require that the iscom is used as an adjuvant (not necessarily for the live virus). This limitation is met by the teachings of the reference. Iosef therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 2, 5-10, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter et al. (U.S. 6,177,081) in view of Morein et al. (U.S. 5,679,354). Claims 1, 2, 6, 9,

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10, and 15 have been described above. The remaining claims specify the components of the iscoms as including lipids and glycosides (e.g. saponins such as Quil A). Claim 5 further requires the presence of a hydrophobic protein or peptide-containing antigen. Claims 7, 8, 13, and 14 are specifically drawn to embodiments wherein the iscom comprises one of Fractions A and/or C of Quil A. The teachings of Wechter have been described above. While Wechter teaches the incorporation of attenuated viruses into iscoms, it does not specify the formula of the iscoms.

Morein provides teachings relating to iscoms for use as an adjuvant for antigens. The reference teaches that iscoms comprise a lipid and a saponin (glycoside). Abstract. The reference also teaches that additional adjuvants may also be included, and that such additional adjuvants may require attachment to a hydrophobic moiety, such as a hydrophobic peptide (protein) for incorporation into the iscom. Columns 5-6. The reference also indicates that the antigens for which iscoms can be used as adjuvants include whole organisms such as viruses. Column 8, lines 4-7. While the reference does not specifically refer to Fractions A and C of Quil A, such fractions would inherently be present in the use of Quil A as a whole. It would therefore have been obvious to those of ordinary skill in the art to have used such iscoms as the iscom adjuvants referred to by Wechter. The combined teachings of these references therefore render the indicated claims obvious.

13. Claims 7, 8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter in view of Morein as applied to claims 1, 2, 5, 6, 9, 10, 13, and 15 above, and further in view of Cox et al. (WO 96/11711). These claims have been described above.

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As indicated above, the teachings of Wechter and Morein do not specifically refer to the use of isolated Fractions A and C of Quil A. However, Cox teaches similar iscom formulations to those of Morein, and indicates that preferred embodiments of such iscoms use as glycosides Fractions A and C of Quil A. Page 4. It would therefore have been obvious to those of ordinary skill in the art to have used such iscoms as the adjuvants for the viruses of Wechter. The combined teachings of the cited references therefore render the claimed inventions obvious.

14. Claims 1, 2, 4, 9, 10, 12, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Woensel et al. (U.S. 5,925,359). These claims are drawn to compositions, and methods of preparing such, comprising a liver microorganism, such as a virus, and an iscom particle. Claims 4 and 12 further require the presence of at least one additional antigenic molecule. Claim 18 is drawn to a method for making the composition comprising the provision of a kit comprising "parts comprising at least one compartment containing the at least one live microorganism and at least one compartment comprising the iscom particle" (i.e. a container comprising the iscom, and a container comprising the virus).

Van Woensel teaches a composition for the vaccination of pigs comprising live attenuated PRRS viruses. See e.g., abstract, claims. The reference teaches that the compositions may be combined with an adjuvant, and specifically suggests the incorporation of the live vaccine antigens in iscoms. Column 5, lines 13-19. Further, the reference suggests the additional combination of the liver attenuated vaccines with other antigens, including antigenic material (i.e. antigenic molecules) from other pathogens. Col. 5, lines 45-59. The teachings of the

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reference therefore suggest the claimed compositions, and thus render the claimed inventions obvious.

15. Claims 5-8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Woensel et al. as applied to claims 1, 2, 4, 9, 10, 12, 15, and 18 above, and further in view of Cox et al. (WO 96/11711). These claims are drawn to the compositions and methods as described above, wherein the iscom particle is one of an iscom (comprising a glycoside- i.e. a saponin such as Quil A or a fraction thereof, at least one lipid, and at least one hydrophobic protein or peptide-containing antigen) or an iscom-matrix (comprising at least one glycoside and at least one lipid). Claims 7, 8, 13, and 14 are specifically drawn to embodiments wherein the iscom comprises one of Fractions A and/or C of Quil A.

As indicated above, Van Woensel teaches compositions comprising an attenuated live virus and an iscom. The reference further teaches that the compositions may comprise additional antigens. However, the reference does not specify the form of the iscoms.

Cox teaches that iscoms may be in the forms of iscoms comprising the glycosides and lipids identified in the rejected claims. See e.g., page 4. The reference also teaches that iscom matrices may be used which incorporate an immunogen. Id. Cox indicates that preferred embodiments of such iscoms use as glycosides Fractions A and C of Quil A. Id. From these teachings, it would have been obvious to those of ordinary skill in the art to have incorporated the additional antigenic molecules (e.g., proteins or peptides) of Van Woensel into the iscom matrices described by Cox, and/or to have used the iscoms described by Cox as the iscom

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adjuvants referred to in Van Woensel. The combined teachings of these references therefore render the claimed inventions obvious.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

Primary Examiner, Art Unit 1648